Additional Use cases/Scenarios for Clinical Trials space
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1. Patient search of clinical trials within and across institutions

A patient has been diagnosed with prostate cancer with a prostate biopsy, and wants to identify any clinical trials that are currently open for patient participation or are pending. Although he lives in Pittsburgh, PA, he would be willing to travel anyplace in the country to participate. He is also curious whether there are pharmaceutical drug studies or other trials that are ongoing in which he could participate, and wants to look at the results of any completed clinical trials in order to educate himself about possible treatments.

He goes the clinical trials website at the University of Pittsburgh. He would like to 1) search for local trials at UPCI 2) search for regional and cooperative trials in Pennsylvania 3) identify any pharmaceutical trials for new drugs and 4) search other academic and cooperative organizations for trials.

He signs on to his health portal, enters the accession number for the tissue sample from his biopsy, and selects the different areas (local, regional, national, pharmaceutical, cooperative) for searching. He wants to look not only at open clinical trials, but also look at completed trials that are reporting data. He hits "search" and after a few seconds, has the results of each of the completed trials that match his tissue pathology, and his clinical picture, as well as information about the appropriate ongoing clinical trials. He selects a few that look promising, emails them to his doctor so that she has that information before their next visit, and saves the complete list to his portal bookmarks. Because he searched based on an accession number, the website also provides him with a link to some information about tissue banking. He prints a universal consent form to authorize the use of his tissue sample in research, to remind himself to ask his doctor about that, too.

This same scenario could be repeated by a physician who does the search as a surrogate for the patient – there would be additional HIPAA issues if the doctor wished to link a particular patient to the search, but otherwise the scenario would be the same.

NOTE: See also an example of a search engine for patients looking for clinical trials at http://www.trialcheck.org/cancertrialshelp/cancertrialshelp.aspx This interface asks the patient for the following information:

- Zip code (so it can list closer trials first)
- Gender
- Ethnicity
- Site of cancer
- Type of cancer (adenocarcinoma, squamous cell, etc depending on the site entered)

- Treatment to date (no chemo, chemo for less than 6 mos, chemo for more than 6 mos)
- Stage
- Patient's age
- Impact on patient's normal daily activity (none to bedridden, with steps in between)

See also the NCI's clinical trial search interface:
http://cancer.gov/Templates/doc.aspx?viewid=CF77634E-36E7-47C2-A88E-9E7B163D71F3&ReqUrl=%2Fsearch%2Fclinical_trials
This asks the patient to specify:

- Type of cancer
- Subtype/stage
- Type of trial (treatment or supportive)
- Zip code
- Distance willing to travel

2. Dissemination of trial-related information to patients and researchers

The point of this scenario is that it may be necessary to share data between institutions on the same clinical trial, but also disseminate information across different trials at different institutions if there are similar drug agents involved.

Based on some adverse events and complications, it has become necessary to modify and clarify the way in which an experimental drug is administered for patient care. This change affects not only the clinical trial that you are running, but could potentially affect other clinical trials that use the same medication (think Vioxx). You need to 1) make the change in the clinical trial protocol that you are running, and in all other trials at the multi-centers that are using the same clinical trial protocol, and 2) you need to identify other trials that you are not running but are likely to have the same kind of complication, and make sure that they are appropriately updated with the most recent administration standards for this drug. Thus, you need to be able to find not just the relevant trials but also the name of the PI for each trial and contact information for that person, in a form that you can use in a mail merge application. You want to send each PI a detailed description of your protocol and the changes you're making in it. You won't necessarily generate this automatically from the clinical trials system, but the system should give you direct access to your original IRB protocol and any subsequent changes.

3. Update the vocabularies and terminologies used in our clinical trial management applications to the new NCI standards.

The NCI has just released new terminology pertaining to an area of clinical trials that we're involved in, and they have also updated the definitions of some existing terminology. Without interfering with our ongoing operations, we must modify our system so that users see the new terminology where appropriate rather than the old. For

a period of time that we specify, our interface should alert users of the system to terms that have new definitions and to new terms. Users must be able to continue to use the same mechanism they're used to in order to look up definitions of unfamiliar terms, and they must also be able to look up or link to any term that has been replaced and a rationale for the replacement.

4. Consent registry

Researchers need to track and maintain consent information about patients to allow for a) searching their medical records for inclusion/exclusion criteria, and b) linking them to existing clinical trials and/or investigators doing research. The system must provide audit trails for review by the IRB and University privacy officers.